

100



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/142,660	12/23/1998	RAINER HINTSCHE	60953/119	2492
26633	7590	08/03/2004		
HELLER EHRMAN WHITE & MCAULIFFE LLP 1666 K STREET,NW SUITE 300 WASHINGTON, DC 20006			EXAMINER SISSON, BRADLEY L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 08/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/142,660	<b>Applicant(s)</b> HINTSCHE ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 71-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-92 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 22 June 2014 has been entered.

### ***Claim Objections***

2. Claim 75 is objected to because of the following informalities: In line 3 of said claim a period (“.”) is found immediately following “binding.” Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 72 recites the limitation that the second molecule is bound to “to a surface of a gap.” It is unclear how anything can be bound to gap, which is understood to be a void. Page 8,

last paragraph, of the specification teaches that the molecules may be positioned “in the gaps between electrodes instead of on the electrodes.”

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 71-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,110 (Williams et al.) in view of WO 93/22678 (Hollis et al.).

10. Williams et al., disclose manufacturing and use of electrodes for the detection of nucleic acids, proteins, antibodies, etc. Column 3, lines 5-6, teaches that the initial gap of the electrode is from, 10 to 75  $\mu\text{m}$ . Column 3, lines 13-18, teach that the electrodes can be treated by bonding, or adsorption of enzymes, as well as specific binding partners “including, but not limited to, antibodies, antigens, DNA or RNA, avidin, biotin, gene probes...” While the gap of the electrode would no doubt diminish by the presence of such binding partners, Williams et al., does not teach that the gap narrows to where it ranges from 1  $\mu\text{m}$  to that of a large molecular complex.

11. Williams et al., do not teach that the electrodes are made of noble metals such as gold, or out of carbon.

12. Hollis et al., page 11, teach that while the gap in the insulating material is 2  $\mu\text{m}$  wide, “importantly, the spacing between the upper and lower electrodes is of the order of the length (or diameter in solution) of the target DNA molecule. Therefore, the ratio of the target DNA to solvent in the interelectrode space is high, thereby giving greater sensitivity to the presence or absence of the target DNA during an electrical measurement.”

13. Hollis et al., page 25, teaches:

Materials which can be incorporated into the surface of the electrodes to provide for direct attachment of probes include electrometal materials, such as gold, niobium oxide, iridium oxide, platinum, titanium, tantalum, tungsten and other metals. These electrometals are capable of forming stable conjugates directly on the plate surface by linkages with organic thiol groups incorporated into the probe, as described in Whitesides et al. (1990) Langmuir 6:87-96 and Hickman et al. (1991) J. Am. Chem. Soc. 113:1128-1132, both of which are incorporated by reference herein.

14. Hollis et al., Figure 1, depicts a device where the electrodes are arranged in a substantially planar manner as well as being stacked. The aspect of the electrode leads being surrounded by a non-conductive substrate speaks to their being insulated from one another.

15. In view of the detailed teachings of the prior art of record, and the motivation for arrange the electrodes such that the gap between the electrodes approximates the size of a large molecular complex, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the sensor and methodologies of Hollis et al., into the disclosure of Williams et al., as such would have resulted in greater sensitivity. Accordingly, and in the absence of convincing evidence to the contrary, claims 71-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,020,110 (Williams et al.) in view of WO 93/22678 (Hollis et al.).

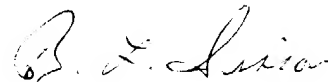
### *Conclusion*

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 97/04313A2 (Garcia et al.) teaches use of electrodes made of carbon and to which a specific binding member has been coated.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
26 July 2004